

In re Application of:  
Yamakawa et al.  
Application No.: 10/749,532  
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Atty Docket No.: INTEL1110(P15140)

### **REMARKS**

Applicant respectfully requests entry of amendments to claims 1-6, 10-12, and 15-19, canceling claims 8, 9, 13, and 14, and adding new claims 32-36. Support for the amendments can be found throughout the specification, including page 4, paragraph [0015] to page 5, paragraph [0017], Figure 1, page 8, paragraph [0028], page 10, paragraph [0034], and the originally filed claims, and, therefore, do not add new matter. Applicants submit that pending claims 1-7, 10-12, 15-19 and 32-36 are in condition for allowance.

Applicants respectfully request that any correction of any errors that may exist in the specification be held in abeyance until allowable subject matter has been identified.

### **Rejection Under 35 U.S.C. §112, Second Paragraph**

Claims 5, 6, 8, 15, and 19 stand rejected under 35 U.S.C. §112, second paragraph as allegedly being indefinite.

Applicants traverse the rejection, including as it might apply to the new and amended claims, and claims dependent therefrom, for the reasons given below.

Claim 5 is alleged to be indefinite for lack of antecedent. While not acquiescing to the reasoning offered in the Action, and to expedite prosecution toward allowance, the claim has been amended so as to not recite the term at issue.

Claim 6 is alleged to be indefinite for lack of antecedent. While not acquiescing to the reasoning offered in the Action, and to expedite prosecution toward allowance, the claim has been amended so as to not recite the term at issue.

Claim 8 has been canceled, so the rejection as applied to this claim is rendered moot.

Claim 15 is alleged to be indefinite for lack of antecedent. While not acquiescing to the reasoning offered in the Action, and to expedite prosecution toward allowance, the claim has been amended.

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Claim 19 is alleged to be indefinite for lack of antecedent. While not acquiescing to the reasoning offered in the Action, and to expedite prosecution toward allowance, the claim has been amended.

For these reasons, Applicants respectfully request that the rejection be withdrawn.

### **Rejections Under 35 U.S.C. §112, First Paragraph**

Claims 1-19 stand rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking written description support.

Applicants traverse the rejection, including as it might apply to the new and amended claims, and claims dependent therefrom, for the reasons given below. As claims 8, 9, 13, and 14 have been canceled, the rejection as applied to these claims is rendered moot.

The Office Action alleges, in pertinent part, that the disclosure does not disclose any peptide that has been identified, providing definitions only, nor does the disclosure describe any kind and/or shape assumed by the surface to contain any kind of target. Further, the Action alleges that the disclosure would not lead the skilled artisan to any particular species, is replete with generalities, and moreover, the Action intimates that representative examples are required to meet the standard for written description. Applicants submit that such allegations are incorrect.

Respectfully, it is not clear from the Action what standard for written description is being required. For example, Applicants submit that requiring the identity of the object of a process (which process identifies the object) be known beforehand, cannot be the standard for written description.

The claims are directed to a method of identifying peptides that have a particular function using compositions that *are known in the art* (i.e., a phage display library, target surfaces, and a surfactant<sup>1</sup>). Applicants submit that the specification describes the invention with all of its

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<sup>1</sup> A substance capable of reducing the surface tension of a liquid in which it is dissolved  
<<http://www.wordreference.com/definition/surfactant>>, last visited, December 20, 2005.

claimed limitations by 1) describing the compositions of the target surfaces (page 4, paragraph [0015] to page 5, paragraph [0016], including shapes (flat, smooth, curved); 2) describing a phage display library (i.e., an art recognized term, e.g., composed of M13 filamentous phage), which phage comprising the library display a different exogenous peptide sequence (at page 5, paragraph [0017] and Figure 1); 3) describing the use of negative selection, including iterations of biopanning, to eliminate undesirable peptide binding products (at page 8, paragraph [0028]); and 4) describing that surfactant monolayers are to be used to select peptides that differentiate surfactant containing surfaces (at page 10, paragraph [0034]), including a figure (Figure 1) that illustrates the result of these process steps. Thus, the specification has provided a description of the steps sufficient to distinguish an infringing method from a non-infringing method *using known compositions*. Cf., University of Rochester v. G.D. Searle & Co., 69 USPQ.2d 1886, 1894 (Fed. Cir. 2004) (holding that an inventor cannot lay claim to subject matter where the method claim entails the use of an *unknown* compound, i.e., where a critical aspect of the method—the *unknown compound defined only by its function*—was hypothetical, there is no written description support).

Further, excluding In re Riat, 140 USPQ 471 (CCPA 1964) and Pfaff v. Wells Electronics Inc., 48 USPQ2d 1641 (S.Ct. 1998),<sup>2</sup> the cases recited in the Action that are alleged to hold that one must sufficiently define subject matter to demonstrate possession are limited to *unknown* compositions. For example, in University of California v. Eli Lilly and Co., 43 USPQ2d 1398 (Fed. Cir. 1997), the cDNA for human insulin had never been characterized. In Amgen Inc. v. Chugai Pharmaceutical Co., Ltd., 18 U.S.P.Q.2d 1016, 1021, (Fed. Cir. 1991), the court explained that a *novel gene* was not adequately characterized by its biological function alone because such a description would represent a mere “wish to know the identity” of the novel

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<sup>2</sup> It is not clear if the citation for the In re Barr case is correct, based on the cite (i.e., 151 USPQ 724) the case is named In re Surrey. In Surrey, the court held that “[t]he sufficiency of a disclosure depends not on the number but rather on the nature of the claimed compounds *per se* and the nature of the supporting disclosures. If a claim covers compounds which are closely related, a comparatively limited disclosure may be sufficient to support it.” If it is In re Barr 170 USPQ 330 (CCPA 1971), the holdings under §112 are directed to enablement, not written description.

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material. In In re Ruschig, 154 USPQ 118, the specific compound that was claimed was never named or otherwise exemplified in the specification as filed.

In contrast, the present claims are directed to a method for identifying an unknown object *using known compositions*: i.e., a phage display library displaying different exogenous peptide sequences which are contacted with a defined surface to identify those peptides which selectively bind to the contacted surface.

Regarding Pfaff, the case is silent with respect to written description in view of unknown and/or known compositions. On the other hand, in Riat, the court reasoned that, on a case-by-case basis, for an art recognized genus, unless the members of the genus are “notoriously unpredictable,” compositions within that genus should possess known properties whether or not all compositions embraced by the claims are disclosed in the specification (i.e., scope is not inconsistent with the invention as disclosed). This comports with the present facts, where phage display libraries are art recognized, and the properties of the libraries, and phages therein, are predictable (e.g., phage display libraries are commercially available).

Further, in view of the case law, the statement that “[a]dequate disclosure, like enablement, **requires representative examples** . . .,” is incorrect. That figures alone, for example, may adequately provide written description is clearly supported in Vas-Cath Inc. v. Mahhurkar, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991) (“[U]nder proper circumstances, drawings *alone* may provide a ‘written description’ of an invention as required by §112,” (emphasis added) where, for example the specification provides literal support for that which is illustrated in the drawing. See, also, Pfaff v. Wells Electronics Inc., 48 USPQ2d 1641 (S.Ct. 1998), (court reasoned that drawings were sufficient to provide written description necessary to support on-sale bar date under 102(b)). And if drawings alone are enough to provide written description as required by §112, the allegation that “[a]dequate disclosure, like enablement, **requires representative examples** . . .,” cannot be the standard.

With respect to Lockwood v. American Airlines, Inc., 41 USPQ2d 1961 (Fed Cir. 1997) the present set of facts are distinguished because Applicants are not suggesting that subject

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matter alleged not to be disclosed, *but would be obvious* over that which is expressly disclosed, should serve as an adequate disclosure. Lockwood, at 1966. Nor are Applicants suggesting that that the disclosure, when combined with knowledge in the art, would now provide to one of skill in the art the ability to *speculate* about the modifications Applicants may have envisioned, but failed to disclose. Id.

Applicants submit that the specification adequately supports the invention as claimed by express disclosure of 1) *known* compositions which make up a target surface, including various surface shapes; 2) using a phage display library (“phage display library” is an art recognized term, further such libraries are commercially available) to contact such a surface, which phage display library comprises phage that display different exogenous peptide sequences (i.e., a predictable property); 3) using negative selection, including iterations of biopanning, to eliminate undesirable peptide binding products; and 4) using surfactant monolayers to select peptides that differentiate surfactant containing surfaces. Further, the positive process steps as disclosed in the specification result in identifying peptides which bind to the contacted surface, as illustrated in Figure 1. As such, one of skill in the art could envision the critical elements of the method of the claimed invention from the present specification, and would appreciate that the inventors were in possession of the invention as claimed at the time the invention was filed.

For these reasons, Applicants respectfully request that the rejection be withdrawn.

Claims 1-19 stand rejected under 35 U.S.C. §112, first paragraph as allegedly lacking written description support.

Applicants traverse the rejection, including as it might apply to the new and amended claims, and claims dependent therefrom, for the reasons given below. As claims 8, 9, 13, and 14 have been canceled, the rejection as applied to these claims is rendered moot.

The Office Action alleges, in pertinent part, that the specification does not provide sufficient guidance to enable one of skill in the art to practice the claimed invention in the absence of undue experimentation. Applicants respectfully submit that the Action fails to

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provide a reasonable explanation(s) as to why the scope of protection provided by the claims is not adequately enabled by the instant specification. For this reason, the initial burden to establish that the invention was unenabled has not been met by the Office Action. See, In re Wright, 27 USPQ2d 1510, at 1513 (Fed. Cir. 1993).

As stated in In re Surrey, 151 USPQ 724 (CCPA 1966), “[t]he sufficiency of a disclosure depends not on the number but rather on the nature of the claimed compounds *per se* and the nature of the supporting disclosures. If a claim covers compounds which are closely related, *a comparatively limited disclosure may be sufficient to support it.*” (Emphasis added). Further, to establish enablement, “[n]othing more than objective enablement is required, and therefore it is irrelevant whether this teaching is provided through broad terminology *or* illustrative examples.” (Emphasis added). In re Marzocchi, 69 USPQ 367, 369 (CCPA 1971).

The amended claims read on phage display libraries (“phage display library” is an art recognized term, including that such libraries have well known/defined properties) and a defined surface (substrates as defined in the specification are well known and widely utilized, see, e.g., U.S. Patent Nos. 6,977,954; 6,977,394; 6,977,419; 6,977,392; 6,975,157; 6,974,738; 6,972,206, and others, including the shapes and geometries that are presented on such surfaces, as well as self-assembled surfactant monolayers which are art recognized, see, e.g., Ulman, Chem Rev (1996) 96:1533-1554; Colorado and Lee, Thiol-based Self-Assembled Monolayers: Formation and Organization, in *Encyclopedia of Materials Science and Technology*, (2001), pp. 9332-9344, Elsevier Science, Ltd., New York, NY). Further, that the scientific community has been able to develop phage which bind to organic, metallic, and/or organo-metallic surfaces does not suggest undue experimentation (e.g., see, Whaley et al., Nature (2000) 405:665 and Gaskin et al., Biotech Lett (2000) 22:1211-1216). Thus, based on the terminology and definitions provided in the instant specification, one of skill in the art would appreciate that a sufficient likelihood of success exists using the recited components and steps to achieve the objectives embraced by the instant claims in view of the teachings of the specification coupled with that which was known in

the prior art (i.e., how to make and use phage display libraries to identify peptides which bind to select surfaces).

Further, because it is well recognized that phage display libraries represent a general class of replicable, mutable chemicals (see, e.g., Exhibit A, Smith and Patrenko, Chem Rev (1997) 97:391-410), this alone would support the conclusion that phage display libraries falling within the scope of the invention would generally have the same likelihood of success in the practice of the invention as claimed (i.e., phage libraries are inherently capable of serving as a way to effect artificial chemical evolution, such that members of the library, in the aggregate, can be used to identify amino acid sequences that specifically bind to various surfaces). See, e.g., Exhibit A and Exhibit B, Russell, et al., Introduction to Phage Biology and Phage Display, in *Phage Display: A Practical Approach*, (2004), (Calckson, ed.), pp.1-26, Oxford University Press, New York, NY. Moreover, as disclosed in Exhibits A and B, there is a general recognition of the efficacy of phage libraries for such purposes, including that general methods were developed at the time the invention was filed for the isolation, identification, cloning, and recombination of phage so as to enable, without undue experimentation, the design and production of phage display libraries. Applicants submit that this position is further supported by the availability of such libraries from commercial sources (e.g., New England Biolabs; Amersham Biosciences; Dyax Corporation; Novagen; Cambrios). Therefore, given the efficacy of such phage display library systems, one of skill in the art could readily extrapolate with certainty that phage display libraries embraced by the claim scope would have the requisite properties to successfully practice the invention as claimed.

Regarding the Wands factors recited, 1) the embraced surfaces are recited in the specification (e.g., at page 5, paragraph [0016]), including the geometric shapes presented by such surfaces (page 5, paragraph [0015]), which are well known, further, the conditions for peptide binding to target and elution are well known (i.e., via adjusting pH, using denaturing agents, proteases etc. (see, e.g., Exhibits A and B)) and/or disclosed (at page 6, paragraph [0019] and page 7, paragraph [0026], moreover, the location and length of the exogenous peptide on the

phage in the library is inherently limited by phage physiology (one of skill in the art would be cognizant of this fact); 2) regarding examples, as stated in In re Marzocchi, requiring of examples is not the standard for enablement, especially where claims cover compositions that are well known/closely related; 3) the position of the Action with regard to claim breadth is unclear, nevertheless, a small subset of representative peptide sequences would be expected, in fact, all that would be necessary for success is one, further, as the peptides that are useful for chemical evolution are synthesized on the surface of phage, it is not clear as to why the limitations of cell expression are recited in the Action; 4) contrary to the position that art recognized techniques are specifically applied for a predetermined target, the claims as recited are also directed to a predetermined target (i.e., surface comprising a surfactant monolayer); 5) the Action attempts to set an unreasonable standard which cannot be correct: it is not clear why it would be a general requirement to know the conformational freedom related to why a peptide binds to a surface before the peptide has been identified, certainly one of skill in the art, given the general success in the use of phage display derived peptides, would predict that phage could be used to identify peptides that bind to surfaces in the absence of undue experimentation: that is all that is required; and 6) it is not clear why for a method which is directed to identifying a peptide, one of skill in the art must know the identity of the peptide beforehand. Applicants submit that targeting of the surface as defined would not be undue, again because one of skill in the art would know how to make and use a phage display library within the scope of the claimed invention.

The claims are enabled because the specification provides appropriate guidance and prediction of function based on a well characterized/well established methodology (i.e., use of a phage display system to identify a binding peptide) such that one of skill in the art could practice the invention as claimed, in the absence of undue experimentation.

For these reasons, Applicants respectfully request that the rejection be withdrawn.



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**Rejections Under 35 U.S.C. §102**

Claims 1-10, 16, 18, and 19 stand rejected under 35 U.S.C. §102(b), as allegedly being anticipated by Naik et al.

Applicants traverse the rejection, including as it might apply to the new and amended claims, and claims dependent therefrom, for the reasons given below. As claims 8, 9, have been canceled, the rejection as applied to these claims is rendered moot.

The Office Action alleges, in pertinent part, that the cited reference teaches the elements as recited in the present claims. However, as recited at page 13 of the Action, Naik does not disclose a surface comprising a surfactant.

The present claims expressly recite “a first surface comprising a self-assembled surfactant monolayer . . .”.

As stated in *Hybritech Inc. v. Monoclonal Antibody, Inc.*, 231 USPQ 81 (Fed. Cir. 1986), “It is axiomatic that for prior art to anticipate under 102 it has to meet every element of the claimed invention.”

Therefore, because the instant claimed method recites a surface comprising a surfactant, the Naik et al. reference does not anticipate the claimed invention.

Failure of the prior art to meet every element of the claimed invention does not meet the standard under 102. For these reasons, Applicants respectfully request that the rejection be withdrawn.

Claims 1, 3-7, 10-12, 15, 18, and 19 stand rejected under 35 U.S.C. §102(e), as allegedly being anticipated by Belcher et al.

Applicants traverse the rejection, including as it might apply to the new and amended claims, and claims dependent therefrom, for the reasons given below.

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The Office Action alleges, in pertinent part, that the cited reference teaches the elements as recited in the present claims. However, as recited at page 13 of the Action, Belcher et al. do not disclose a surface comprising a surfactant.

The present claims expressly recite “a first surface comprising a self-assembled surfactant monolayer . . .”.

As stated in *Hybritech Inc. v. Monoclonal Antibody, Inc.*, 231 USPQ 81 (Fed. Cir. 1986), “It is axiomatic that for prior art to anticipate under 102 it has to meet every element of the claimed invention.”

Therefore, because the instant claimed method recites a surface comprising a surfactant, the Belcher et al. reference does not anticipate the claimed invention.

Failure of the prior art to meet every element of the claimed invention does not meet the standard under 102. For these reasons, Applicants respectfully request that the rejection be withdrawn.

Claims 1, 4-7, 18, and 19 stand rejected under 35 U.S.C. §102(b), as allegedly being anticipated by Lee et al.

Applicants traverse the rejection, including as it might apply to the new and amended claims, and claims dependent therefrom, for the reasons given below.

The Office Action alleges, in pertinent part, that the cited reference teaches the elements as recited in the present claims. However, as recited at page 13 of the Action, Lee et al. do not disclose a surface comprising a surfactant.

The present claims expressly recite “a first surface comprising a self-assembled surfactant monolayer . . .”.

As stated in *Hybritech Inc. v. Monoclonal Antibody, Inc.*, 231 USPQ 81 (Fed. Cir. 1986), “It is axiomatic that for prior art to anticipate under 102 it has to meet every element of the claimed invention.”

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Therefore, because the instant claimed method recites a surface comprising a surfactant, the Lee et al. reference does not anticipate the claimed invention.

Failure of the prior art to meet every element of the claimed invention does not meet the standard under 102. For these reasons, Applicants respectfully request that the rejection be withdrawn.

### **Rejections Under 35 U.S.C. §103**

Claims 1-16, 18, and 19 stand rejected under 35 U.S.C. §103(a), as allegedly being unpatentable over any one of Naik et al., Belcher et al., or Lee et al. in view of Puentes et al.

Applicants traverse the rejection, including as it might apply to the new and amended claims, and claims dependent therefrom, for the reasons given below. As claims 8, 9, 13, and 14 have been canceled, the rejection as applied to these claims is rendered moot.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First there must be some suggestion or motivation in the references themselves or in knowledge generally available to one of skill in the art, to modify the reference or combine the reference teachings. Second, there must be a reasonable expectation of success. And, finally the prior art reference (or references when combined) must teach all claim limitations. The teaching or suggestion and reasonable expectation of success must both be found in the prior art and not in Applicants' disclosure. (See MPEP §706.02(j)).

Applicants submit that because the cited references do not teach all the claim limitations, one of skill in the art would not be motivated to combine the reference teachings.

The Office Action alleges, in pertinent part, that each of Naik, Belcher, and Lee is silent with respect to a surface comprising a surfactant. The Action then provides Puentes to cure the deficiency identified in the primary references. However, review of Puentes demonstrates that the reference does not teach self-assembled surfactant monolayers, an element presently recited in the claims.

As recited in the specification at page 10, paragraph [0034], surfaces are composed of a surfactant, where such surfactants are self-assembled monolayers (SAMs). Such self-assembly requires chemisorption of the of the surfactant to the solid surface (see, e.g., Ulman (1996); Colorado and Lee (2001)), it is well known in the art that typically this is accomplished by either growing the SAM from solution or from the gas phase (Colorado and Lee (2001)).

Puentes et al. teach that organometallic precursors are injected into a hot surfactant mixture (at page 2115, column 2), where the surfactant concentrations are adjusted to control the growth rates of the crystals. The resulting surface does not comprise a separate surfactant monolayer which covers the solid surface, as would be the case for a SAM, but instead is integrated with the formed crystals to produce the various nanorods and spherical shaped nanocrystals as described. Further, rapid injection of organometallic agents in hot solvent results in rapid nucleation, including the rapid decomposition of the monomers in solution (at page 2115, column 3). Again, supporting the fact that the resulting surface does not comprise a SAM.

Because the teachings of Puentes would not result in a target surface comprising self-assembled monolayers when combined with the teachings of Naik, Belcher, and Lee, one of skill in the art would not have an expectation of success since the invention as claimed would not be achieved in view of such teachings. Therefore, one of skill in the art would not be motivated to combine such teachings.

Applicants submit that because there is no reasonable expectation of successfully achieving the invention as claimed, there is no motivation to combine the cited references, thus, no *prima facie* case for obviousness exists. For these reasons, Applicants respectfully request that the rejection, including as it might be applied against the amended claims, be withdrawn.

Claim 17 stands rejected under 35 U.S.C. §103(a), as allegedly being unpatentable over any one of Naik et al., or Belcher et al., or Lee et al., in view of Freeman et al.

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Applicants traverse the rejection, including as it might apply to the new and amended claims, and claims dependent therefrom, for the reasons given below.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First there must be some suggestion or motivation in the references themselves or in knowledge generally available to one of skill in the art, to modify the reference or combine the reference teachings. Second, there must be a reasonable expectation of success. And, finally the prior art reference (or references when combined) must teach all claim limitations. The teaching or suggestion and reasonable expectation of success must both be found in the prior art and not in Applicants' disclosure. (See MPEP §706.02(j)).

Applicants submit that because the cited references do not teach all the claim limitations, one of skill in the art would not be motivated to combine the reference teachings.

The Office Action alleges, in pertinent part, that each of Naik, Belcher, and Lee is silent with respect to a surface comprising Teflon. The Action then provides Freeman et al. to cure the deficiency identified in the primary references. However, review of Freeman et al. demonstrates that the reference is silent with respect to surfactants.

Because the teachings of Freeman et al. would not result in a target surface comprising self-assembled monolayers when combined with the teachings of Naik, Belcher, and Lee, one of skill in the art would not have an expectation of success since the invention as claimed would not be achieved in view of such teachings. Therefore, one of skill in the art would not be motivated to combine such teachings.

Applicants submit that because there is no reasonable expectation of successfully achieving the invention as claimed, there is no motivation to combine the cited references, thus, no *prima facie* case for obviousness exists. For these reasons, Applicants respectfully request that the rejection, including as it might be applied against the amended claims, be withdrawn.

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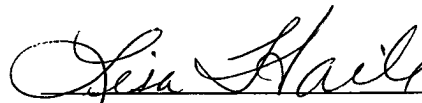
**Conclusion**

In view of the above amendments and remarks, Applicants submit that pending claims 1-7, 10-12, 15-19, and 32-36 are in condition for allowance. The Examiner is invited to contact Applicants' undersigned representative if there are any questions relating to this submission.

No fee is deemed necessary with the filing of this paper. However, the Commissioner is hereby authorized to charge any fees required by this submission, or credit any overpayments, to Deposit Account No. 07-1896 referencing the above-identified docket number. A duplicate copy the Transmittal Sheet is enclosed.

Respectfully submitted,

Date: December 28, 2005



Lisa A. Haile, J.D., Ph.D.  
Registration No. 38,347  
Telephone: (858) 677-1456  
Facsimile: (858) 677-1465

DLA PIPER RUDNICK GRAY CARY US LLP  
ATTORNEYS FOR INTEL  
4365 Executive Drive, Suite 1100  
San Diego, California 92121-2133  
**USPTO Customer Number 28213**